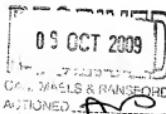


PATENT COOPERATION TREATY

SEARCHING AUTHORITY

JRD
John Michael O
ary Square

2RA
STAGNE



Applicant's or agent's file reference

P050903WO

International application No.

PCT/GB2009/001448

Applicant

CILAG GMBH INTERNATIONAL

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing (day/month/year)	02/10/2009
FOR FURTHER ACTION	See paragraphs 1 and 4 below
International filing date (day/month/year)	10/06/2009

1. The applicant is hereby notified that the International search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70

For more detailed instructions, see the notes on the accompanying sheet.

2. The applicant is hereby notified that no International search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of 18 months from the priority date, the International application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the International application, or of the priority claim, must reach the International Bureau as provided in Rules 90(b).1 and 90(b).3, respectively, before the completion of the technical preparations for International publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority

European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 espn nl,
Fax. (+31-70) 340-3016

Authorized officer

Elisabetta Sulis

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file the amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 295).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/ is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/ may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]: "Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]: "Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]: "Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or "Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]: "Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1bis(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43bis.1(c)).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P050903WO	FOR FURTHER ACTION	
International application No. PCT/GB2009/001448	International filing date (day/month/year) 10/06/2009	(Earliest) Priority Date (day/month/year) 19/06/2008
Applicant		
CILAG GMBH INTERNATIONAL		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 6 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the language, the international search was carried out on the basis of:
 - the International application in the language in which it was filed
 - a translation of the International application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
- b. This international search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43.6(b)(a)).
- c. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. **Certain claims were found unsearchable** (See Box No. II)

3. **Unity of Invention is lacking** (see Box No III)

4. With regard to the title,

- the text is approved as submitted by the applicant
- the text has been established by this Authority to read as follows:
REUSABLE AUTO-INJECTOR

5. With regard to the abstract,

- the text is approved as submitted by the applicant
- the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 3
 - as suggested by the applicant
 - as selected by this Authority, because the applicant failed to suggest a figure
 - as selected by this Authority, because this figure better characterizes the invention
- b. none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB2009/001448

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

An injection device comprises a first sub-assembly. The first sub-assembly comprises a chamber (116) for holding a fluid. The chamber comprises an inner surface and an exit aperture (114). The first sub-assembly comprises a stopper (112) movably disposed within the chamber and having an outer surface substantially in contact with the inner surface about its perimeter. The first sub-assembly comprises an adapter (118) adapted to transfer fluid into the chamber.

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2009/001448

A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61M5/178 A61M5/20
 ADD. A61J1/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ✓	US 2001/037087 A1 (KNAUER PETER M [US]) 1 November 2001 (2001-11-01) paragraphs [0026] - [0038]; figures 1-9 -----	1-18
X ✓	US 6 090 070 A (HAGER JOERG-CHRISTIAN [DE]; GEBHART KURT [DE]; LOEWENICH HELMUT [DE];) 18 July 2000 (2000-07-18) column 16, line 19 - column 19, line 29; figures 1-9 -----	1-18
X ✓	US 2006/184137 A1 (REYNOLDS DAVID L [CA]) 17 August 2006 (2006-08-17) figures 27-40 -----	1-6, 16-18 7-15 ----
Y		

Further documents are listed in the continuation of Box C.

See patent family annex.

Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubt on priority, claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or inventive if it is considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the International search report
28 September 2009	02/10/2009
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patenttaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040 Fax. (+31-70) 340-3016	Authorized officer Björklund, Andreas

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2009/001448

C(Continuation): DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y ✓	WO 2007/036676 A1 (CILAG GMBH INT [CH]; HABESHAW ROSIE LOUISE [GB]; JOHNSTON DAVID MAXWEL) 5 April 2007 (2007-04-05) page 8, line 8 - page 13, line 2; figures 1-8 -----	7-15
Y ✓	FR 2 654 938 A1 (GLAXO GROUP LTD [GB]) 31 May 1991 (1991-05-31) page 19, line 22 - page 20, line 17; figures 1-24 -----	12-15

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2009/001448

Patent document cited in search report		Publication date	Patent family member(s)	Publication date	
US 2001037087	A1	01-11-2001	NONE		
US 6090070	A	18-07-2000	AU BR CA CZ DE EP HU JP NO NZ ZA	1266397 A 9700930 A 2197395 A1 9700415 A3 19705189 A1 0857491 A1 9700427 A2 10225516 A 970606 A 314211 A 9701138 A	20-08-1998 08-12-1998 12-08-1998 12-08-1998 13-08-1998 12-08-1998 28-06-1999 25-08-1998 11-08-1998 28-01-1999 28-10-1998
US 2006184137	A1	17-08-2006	AU CA WO EP JP NZ	2004206779 A1 2513165 A1 2004064706 A2 1592381 A2 2006515201 T 541530 A	05-08-2004 05-08-2004 05-08-2004 09-11-2005 25-05-2006 29-06-2007
WO 2007036676	A1	05-04-2007	AU BR CA CN EA EP JP	2005336826 A1 PI0520572 A2 2623962 A1 101346157 A 200800939 A1 1928523 A1 2009509605 T	05-04-2007 19-05-2009 05-04-2007 14-01-2009 29-08-2008 11-06-2008 12-03-2009
FR 2654938	A1	31-05-1991	AR AT AU AU BE BR CA CH CZ DE DK ES FI GB GR HK HU	246185 A1 400925 B 639955 B2 6691290 A 1003835 A5 9006006 A 2030742 A1 687234 A5 9702029 A3 4037418 A1 281990 A 2038088 A6 905832 A 2239180 A 90100824 A 19295 A 61207 A2	29-07-1994 25-04-1996 12-08-1993 06-06-1991 23-06-1992 24-09-1991 29-05-1991 31-10-1996 11-08-1999 29-05-1991 29-05-1991 01-07-1993 29-05-1991 26-06-1991 17-04-1992 17-02-1995 28-12-1992
FR 2654938	A1		IE IL IN IT JP JP LU NL NO NZ PL	904240 A1 96487 A 179332 A1 1243541 B 3222962 A 3399524 B2 87851 A1 9002598 A 905125 A 236219 A 287996 A1	05-06-1991 26-05-1995 27-09-1997 16-06-1994 01-10-1991 21-04-2003 25-08-1992 17-06-1991 29-05-1991 23-12-1992 12-08-1991

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2009/001448

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
	PT	96005 A	31-08-1992
	SE	469262 B	14-06-1993
	SE	9003776 A	29-05-1991
	RU	2108116 C1	10-04-1998
	US	5137516 A	11-08-1992
	ZA	9009514 A	27-11-1991

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Applicant's or agent's file reference
see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

International application No.
PCT/GB2009/001448

International filing date (day/month/year)
10.06.2009

Priority date (day/month/year)
19.06.2008

International Patent Classification (IPC) or both national classification and IPC
INV. A61M5/178 A61M5/20
ADD. A61J1/20

Applicant
CILAG GMBH INTERNATIONAL

FOR FURTHER ACTION See paragraph 2 below

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0
Fax: +49 89 2399 - 4465

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Björklund, Andreas

Telephone No. +49 89 2399-7310



WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/GB2009/001448

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of:
 the international application in the language in which it was filed
 a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 a sequence listing
 table(s) related to the sequence listing
 - b. format of material:
 on paper
 in electronic form
 - c. time of filing/furnishing:
 contained in the international application as filed.
 filed together with the international application in electronic form.
 furnished subsequently to this Authority for the purposes of search.
4. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/GB2009/001448

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or
Industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	<u>1-18</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-18</u>
Industrial applicability (IA)	Yes: Claims	<u>1-18</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1 US 2001/037087 A1 (KNAUER PETER M [US]) 1 November 2001 (2001-11-01)

D2 US 6 090 070 A (HAGER JOERG-CHRISTIAN [DE]; GEBHART KURT [DE]; LOEWENICH HELMUT [DE];) 18 July 2000 (2000-07-18)

D3 US 2006/184137 A1 (REYNOLDS DAVID L [CA]) 17 August 2006 (2006-08-17)

D4 WO 2007/036676 A1 (CILAG GMBH INT [CH]; HABESHAW ROSIE LOUISE [GB]; JOHNSTON DAVID MAXWEL) 5 April 2007 (2007-04-05)

D5 FR 2 654 938 A1 (GLAXO GROUP LTD [GB]) 31 May 1991 (1991-05-31)

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject - matter of claims 1-18 is not new in the sense of Article 33(2) PCT.

2.1. The document D1 discloses (the references in parentheses applying to this document):

An injection device (figs. 1-9) comprising:

a first sub-assembly (300) comprising:

a chamber (302) for holding a fluid, said chamber comprising an inner surface and an exit aperture;

a stopper (303) movably disposed within the chamber and having an outer surface substantially in contact with the inner surface about its perimeter; and

an adapter (301) adapted to transfer fluid into the chamber.

The subject-matter of claim 1 is therefore not new (Article 33(2) PCT).

2.2. Also the documents D2-D3 (see references in search report) disclose the subject-matter of claim 1. It is noted that the wording of claim 1 is so broad that also a regular syringe deprives the subject-matter of claim 1 of novelty (Article 33(2) PCT) since the piston rod of the syringe can be regarded as the adapter.

2.3. The same reasoning applies, mutatis mutandis, to the subject - matter of the corresponding independent claim 17, which therefore is also considered not new (Article 33(2) PCT).

2.4. The documents D1-D3 (see references in search report) disclose the subject-matter of claim 16 (Article 33(2) PCT).

2.5. Claims 1 and 17 have been drafted as independent claims and have at least partly overlapping scope. Drafting such a plurality of independent claims with overlapping scope makes it impossible to clearly delimit the subject matter which could represent the invention for which protection is sought, so that the claims as a whole fail to comply with the clarity and conciseness requirements of Article 6 PCT.

2.6. The subject-matter of claims 1 and 17 is not clear (Article 6 PCT) since the last lines of the claims define by a result to be achieved, i.e. "adapter adapted to transfer fluid into the chamber". However, in the present application it would have been possible to define the technical features necessary for achieving this result (PCT Guidelines 5.35).

2.7. The scope of claim 1 is much broader than what is actually justified by the disclosure of the application (Article 6 PCT and PCT guidelines 5.43). The application discloses only one possible injection device, namely an auto-injector device, whereas the claims encompass any injection device. That the scope of the claims is much broader than what is justified is underlined by the description which describes that the problem to be solved is to overcome the complicated and expensive manufacturing process of auto-injectors.

3. Dependent claims 2-15 and 18 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, since they merely define trivial design options for injection devices which are known in the art, see documents D1-D5 and the corresponding passages cited in the search report.

4. Claim 1 is not drafted in the two-part form (Rule 6.3(b) PCT) and none of the claims are provided with reference signs (Rule 6.2(b) PCT).

5. Documents D1-D3 are not mentioned in the description (Rule 5.1(a)(ii) PCT).

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information

For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.

Amending claims under Art. 19 PCT

Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.

Filing a demand for international preliminary examination

In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT).

If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).

Filing informal comments

After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.

End of the international phase

At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPER (international preliminary examination report).

Relevant PCT Rules and more information

Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003